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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,108	03/29/1999	FILIPPA BRUGLIERA	11658	1756

7590

08/14/2002

SCULLY SCOTT MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY, NY 11530

EXAMINER

NELSON, AMY J

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 08/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/142,108

Applicant(s)

BRUGLIERA ET AL.

Examiner

Amy Nelson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Specification

1. This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Summary of the Invention.
- (g) Brief Description of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Applicant must amend the Specification to insert the Appropriate Section Headings.

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2. The material of Table 7 is inappropriate for a table. Table 7 should be deleted from the specification, and resubmitted as an additional Drawing. Tables 8-12 should be renumbered and the Brief Description of Drawings should be amended accordingly.

Claim Objections

3. Claims 34-37 are objected to because of the following informalities:

At Claims 34-37, "a transgenic plant" should be changed to --the transgenic plant-- because it refers to a previous claim.

At Claim 34, "The cut flower" should be changed to --A cut flower--.

At Claim 35, "The seed" should be changed to --A seed--.

At Claim 36, "The fruit" should be changed to --A fruit--.

At Claim 37, "The leaf" should be changed to --A leaf--.

Claim Rejections - 35 USC § 112

4. Claims 1-24, and 26-37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 11/3/00. Applicant's arguments filed 5/7/01 have been fully considered but they are not persuasive.

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Applicant asserts that WO93/20206 provides evidence that SEQ ID NO:26 effects a petal color change from 55D-56C/D to 54A-55A in transgenic petunia. In contrast, SEQ ID NO:1 effects a more dramatic color change from 69B/73D to 67B/68A to the whole corolla, as shown at pages 47-48 and Table 5 of the specification. Also, page 50 and Table 6 of the specification shows that TLC analysis revealed production of 3'-hydroxylated cyanidin, peonidin and queritin in the transgenic petals. Furthermore, pages 55, 67 and 80 of the specification show that SEQ ID NO:14, SEQ ID NO:5 and SEQ ID NO:3 (from rose, snapdragon and carnation) each result in dramatic color changes in the corolla of transgenic plants. Hence, the instant specification teaches several different nucleic acids encoding a F3'H that hydroxylates flavonoid compounds more efficiently than the F3'H encoded by SEQ ID NO:26. Also, Applicant submits that the instant specification describes a large number of nucleic acid molecules encoding F3'H from a large number of ornamental plant species. Hence, Applicant has satisfied the written description requirement (response, p. 12-14).

Examiner responds that the teachings of WO93/20206 indicates that a color change from light pink to red was observed with SEQ ID NO:26 (bottom of p. 33). It is unclear how this color change can be clearly designated to be less significant than the color change from pale lilac to dark pink with SEQ ID NO:1 and the other nucleic acids of the instant specification. Further, Applicant provides no comparative data with respect to production of 3'-hydroxylated compounds, and hence Applicant fails to present convincing evidence that any of the nucleic acids of the instant specification, SEQ ID NO:1 or otherwise, encodes an F3'H that effects more

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efficient hydroxylation of flavonoid compounds. As at least some of the instant claims are directed to a subgenus of nucleic acids encoding F3'H that effects more effective hydroxylation of flavonoid compounds, Applicant's argument that the instant specification describes a large number of the broad genus of nucleic acids encoding F3'H is off point. Therefore, the rejection is maintained.

5. Claims 1-24, and 26-39 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated nucleic acid molecule encoding a plant F3'H, a gene construct and transgenic plant comprising said nucleic acid molecule, and a method for altering F3'H activity and flower color in transgenic plants with said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 11/3/00. Applicant's arguments filed 5/7/01 have been fully considered but they are not persuasive.

Applicant argues that, as discussed above, the instant specification teaches a number of nucleic acid molecules that effect hydroxylation of flavonoid compounds more efficiently than the F3'H encoded by SEQ ID NO:26, and the instant specification also teaches nucleic acid molecules that share sequence similarity with and that hybridize to the disclosed nucleic acid molecules (response, p. 14). Examiner responds, as above, that the evidence presented by

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Applicant does not convincingly demonstrate that the nucleic acids of Applicant encode F3'H enzymes that are more efficient at hydroxylation of flavonoid compounds. Applicant is invited to submit side-by-side evidence to demonstrate the functional distinction. Further, Applicant provides no sequence analysis to show that the nucleic acids of the instant specification are structurally related to each other and structurally unrelated to SEQ ID NO:26, hence constituting a structurally and functionally distinct class of F3'H nucleic acids that are readily recognizable.

6. Claims 2-24, and 26-37 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 11/3/00. Applicant's arguments filed 5/7/01 have been fully considered but they are not persuasive. Applicant asserts that the rejections of record have been addressed by the claim amendments, however the following rejections remain.

At Claim 2, lines 3-4, the phrase "control production" is indefinite. It is not clear what is encompassed by "control," and how the nucleic acid sequences control flavonoid production. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claims 3-13, line 3, the term "similarity" is unclear in the present context. Nucleic

acid sequences are being compared, which can be compared only in terms of --identity--.

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At Claims 3-13, lines 3-6, the phrase “low stringency conditions” is indefinite. Applicant has not remedied the meaning of the phrase because no time is specified for either the hybridization or wash step, and no temperature is specified for the wash step.

In Claim 26, the multiple use of “or” at lines 7 (one occurrence), 10 (two occurrences), 12 (one occurrence), and 14 (one occurrence) renders the Markush language improper. The alternatives should be included as additional Markush members.

At Claim 26, line 13, the phrase “low stringency conditions” is indefinite. Applicant has not remedied the meaning of the phrase because no time is specified for either the hybridization or wash step, and no temperature is specified for the wash step.

In Claim 29, line 2, “a nucleotide sequence or complementary nucleotide sequence selected from” is improper Markush language. Also, the multiple use of “or” at lines 6 (one occurrence), 9 (two occurrences), and 11 (one occurrence), and 12 (one occurrence) renders the Markush language improper. The alternatives should be included as additional Markush members.

At Claim 29, line 12, the phrase “low stringency conditions” is indefinite. Applicant has not remedied the meaning of the phrase because no time is specified for either the hybridization or wash step, and no temperature is specified for the wash step.

At Claim 31, line 1, the phrase “capable of modulating” is indefinite because it is unclear whether or not it modulates, and how it modulates. Appropriate correction is required to clarify the claimed invention.

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In Claim 32, the multiple use of “or” at lines 6 (one occurrence), 9 (two occurrences), 11 (one occurrence), and 13 (one occurrence) renders the Markush language improper. The alternatives should be included as additional Markush members.

At Claim 32, line 12, the phrase “low stringency conditions” is indefinite. Applicant has not remedied the meaning of the phrase because no time is specified for either the hybridization or wash step, and no temperature is specified for the wash step.

At Claim 33, line 2, “a sequence of nucleotides selected from...” is improper Markush language. Also, the multiple use of “or” at lines 7 (one occurrence), 10 (two occurrences), 12 (one occurrence), and 14 (one occurrence) renders the Markush language improper. The alternatives should be included as additional Markush members.

At Claim 33, line 13, the phrase “low stringency conditions” is indefinite. Applicant has not remedied the meaning of the phrase because no time is specified for either the hybridization or wash step, and no temperature is specified for the wash step.

Claim Rejections - 35 USC § 102

7. Claims 26-37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Holton *et al.* (WO 93/20206). This rejection is repeated for the reasons of record as set forth in the last

Official action mailed 11/3/00. Applicant's arguments filed 5/7/01 have been fully considered but they are not persuasive.

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Applicant asserts that Holton discloses SEQ ID NO:26, but does not disclose nucleic acid molecules encoding a F3'H which effects more efficient hydroxylation of flavonoids compounds than does the F3'H encoded by SEQ ID NO:26. Hence, the Holton reference does not anticipate the claimed invention (response, p. 15). Examiner responds that Claims 26-37 are not so limited, and therefore the rejection is maintained. The isolated nucleic acid molecules of Holton have at least 60% similarity, or would hybridize under low stringency conditions to the disclosed nucleic acid molecules of the instant invention of SEQ ID NO:1, 3, 5, 7, 9, 14, 16, 18, 20, 22, and 24. Therefore, the rejection is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM.

The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

A handwritten signature in cursive script that reads "Amy Nelson".

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

Amy J. Nelson, Ph.D.

August 13, 2002
